UNITED STATES DISTRICT COURT

EASTERN DISTRICT OF NEW YORK

UNITED STATES OF AMERICA

Plaintiff,

v.

B4B EARTH TEA LLC, a limited liability company;

B4B CORP., a corporation; and

ANDREW MARTIN SINCLAIR, individually and as an officer of B4B EARTH TEA LLC and B4B CORP.,

Defendants.

UNITED STATES' COMBINED OPPOSITION TO DEFENDANT SINCLAIR'S MOTIONS TO DISMISS

Civil Action No.: 22-CV-1159

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I. INTRODUCTION

The Defendants manufacture and sell a drink, which they call Earth Tea. They have claimed, among other things, that Earth Tea can prevent and treat COVID-19. Under the relevant law, because they make such claims, Earth Tea is regulated as a drug. But no government agency has ever approved the sale of the drug, nor does the medical community recognize Earth Tea as safe and effective against COVID-19. The Defendants' sale of Earth Tea thus violates the Federal Food, Drug, and Cosmetic Act.

What is more, the Defendants cannot support these drug claims about Earth Tea with competent and reliable scientific evidence. Making those claims is thus deceptive. Defendants' conduct therefore violates the Federal Trade Commission Act.

Defendant Andrew Martin Sinclair has filed two motions to dismiss: one filed under Rule 12(b);[1] another purportedly filed under Rule 11.[2] Nothing in Defendants' motions calls into

[1] Although Defendant Sinclair's motion under Rule 12(b) fails to specify the subsection of Rule 12(b) under which he is proceeding, the United States interprets Defendant Sinclair's motion to be under Rule 12(b)(6), because it does not present arguments that implicate the other subsections, such as those relating to jurisdiction, venue, service of process, or failure to join a party. *See* Fed. R. Civ. P. 12(b)(1-7).

[2] The United States is treating Defendant Sinclair's Rule 11 motion as a motion to dismiss pursuant to Rule 12. Based on the motion itself, it appears that Defendant Sinclair is arguing that the United States has not stated facts in the Complaint sufficient to support the allegation that Defendants' marketing of Earth Tea is deceptive. That argument sounds in Rule 12(b)(6). The United States addresses that argument in the text of this brief. To the extent that Mr. Sinclair is, in fact, moving pursuant to Rule 11, however, such a motion must fail. First, Defendant Sinclair has not complied with the "safe-harbor" provision of Rule 11 itself. Pursuant to that provision, before a party may present a Rule 11 motion to the court, the party must first serve such a motion on the opposing party and allow the opposing party 21 days to make corrections to any pleading, if appropriate. *See* Fed. R. Civ. Pro. 11(c)(2). The safe-harbor provision is a "strict procedural requirement." *Star Market Mgmt., Inc. v. Koon Chun Hing Kee Soy & Sauce Factory, Ltd.*, 682 F.3d 170, 175 (2d Cir. 2012). A defendant's failure to abide by the provision dooms a Rule 11 motion. Second, a Rule 11 motion may be granted only if the moving party establishes that it is

question any of the relevant facts asserted in the Complaint, including the claims Defendants have been making about Earth Tea's effectiveness against COVID-19. Nor do the motions call into question that Earth Tea has not satisfied the regulatory requirements that must be met before it can be marketed as a prevention or cure for a disease. The motions should thus be rejected.

In his Rule 12 motion, Defendant Sinclair appears to assert that Earth Tea is a dietary supplement, as opposed to a drug. But this claim fails: the numerous statements in Earth Tea's labeling representing that Earth Tea prevents, treats, and cures a specific disease (infection with COVID-19)[3] render Earth Tea a drug under the Food, Drug, and Cosmetic Act ("FDCA"), and thereby render the dietary supplement regulations inapplicable.[4]

The crux of Defendant Sinclair's Rule 11 Motion also proceeds from the premise that dietary supplement regulations govern the United States' claims in this case. Defendant Sinclair invokes a statement relating to the Dietary Supplement Health and Education Act of 1994

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patently clear that the opposing party has no chance of succeeding on its claims. *See, e.g.*, *Galicia v. Tobiko Restaurant*, *Inc.*, 16-cv-4074 (ADS)(SIL), 2017 WL 2437260, at *5 (E.D.N.Y. Jun. 3, 2017). As explained throughout the text, the claims the United States brings are valid and well supported by the evidence and the law. Third, Rule 11 is not a substitute for a motion to dismiss. *See Safe-Strap Co., Inc. v. Koala Corp.*, 270 F. Supp. 2d 407, 412 (S.D.N.Y. 2003). It is premature – even improper – for a party to bring a Rule 11 motion before it challenges the legal sufficiency of the claims. *See id.* at 412-13. Other rules – like Rule 12 – are available for that purpose and are to be used instead. *See* Fed. R. Civ. P. 11 Advisory Committee's Note (1993 Amendments).

[3] *See, e.g.*, Compl. ¶¶ 21-34.

[4] Before the Complaint was filed, government agencies did warn Defendant Sinclair that his product was a drug subject to government regulation. *See* Compl. ¶¶ 36–37; Feb. 18, 2021 Joint FDA/FTC Warning Ltr. to B4B Corp. at 1 ("The FDA has observed that your website https://www.b4bcorp.com offers the product Earth Tea Extra Strength for sale in the United States and that this product is intended to mitigate, prevent, treat, diagnose, or cure COVID-19 in people. Based on our review, this product is an unapproved new drug sold in violation of section 505(a) of the Federal Food, Drug, and Cosmetic Act (FDCA), 21 U.S.C. § 355(a)."), available at https://www.fda.gov/inspections-compliance-enforcement-and-criminal-investigations/warning-letters/b4b-corp-609521-02182021.

("DSHEA"), which applies only to dietary supplements, not drugs. This excerpt indicates that, under DSHEA, "the burden of proof shall be on the United States to establish that an article or other such matter is false or misleading." Rule 11 Mot. at 2. This provision does not apply here, however, because the defendants' labeling for Earth Tea causes it to be an unapproved new drug.

Defendant Sinclair also claims that the United States has not brought forward proof that customers were misled or deceived. Such proof is not required at the motion to dismiss stage. What is more, when seeking injunctive relief under the FDCA, Federal Trade Commission Act ("FTC Act"), and the COVID-19 Consumer Protection Act ("COVID-19 CPA"), the United States need not establish that any particular consumer suffered harm.

Next, Defendant Sinclair invokes the Fifth and Fourteenth Amendments to the U.S. Constitution and a state statute. These provisions do not apply. And even if the Fifth Amendment were to apply, relevant case law establishes that a Due Process Clause claim is meritless in this context.

Finally, Defendant Sinclair has not retained an attorney to represent the corporate Defendants. Well settled law states that corporate entities must be represented by an attorney; Defendant Sinclair cannot act on their behalf.

In light of the foregoing, Defendant Sinclair's Motions to Dismiss should be denied.

II. STANDARD OF REVIEW

It is well settled law that motions to dismiss under Rule 12(b) should be denied "unless it appears beyond doubt that the plaintiff can prove no set of facts in support of its claim which would entitle it to relief." *Conley v. Gibson*, 355 U.S. 41, 45-46 (1957); *accord Navin v. HSBC Bank USA, Nat. Ass'n*, 581 F. App'x 57, 57 n.1 (2d Cir. 2014) ("To survive a motion to dismiss, a complaint must contain sufficient factual matter, accepted as true, to state a claim to relief that is plausible on its face.") (quoting *Ashcroft v. Iqbal*, 556 U.S. 662, 678 (2009)); *Pearson v.*

Thompson, Civ. No. AW 8:04-cv-3600, 2005 WL 8174733, at *2 (D. Md. Jul. 28, 2005) (*quoting Conley*, 355 U.S. at 45-46)). "In reviewing a 12(b)(6) motion, the Court must 'construe the complaint liberally, accepting all factual allegations in the complaint as true, and drawing all reasonable inferences in the plaintiff's favor." *Ostermeier-McLucas v. Rite Aid Hdqtrs. Corp.*, 549 F. Supp. 3d 276, 281 (2d Cir. 2021) (quoting *Bacon v. Phelps*, 961 F. 3d 533, 540 (2d Cir. 2020)). A motion to dismiss must be denied if the complaint pleads "'enough facts to state a claim to relief that is plausible on its face,' . . . and 'allow[] the court to draw the reasonable inference that the defendant is liable for the misconduct alleged.'" *Rush v. Canfield*, 649 F. App'x 70, 70 (2d Cir. 2016) (quoting *Bell Atl. Corp. v. Twombly*, 550 U.S. 544, 570 (2007) and *Iqbal*, 556 U.S. at 678).

III. ARGUMENT

A. DEFENDANT SINCLAIR'S ARGUMENTS BASED ON FDA'S DIETARY SUPPLEMENT REGULATIONS FAIL BECAUSE THEY ARE IRRELEVANT TO THE CLAIMS IN THE UNITED STATES' COMPLAINT, WHICH ALLEGE THAT EARTH TEA IS AN UNAPPROVED NEW DRUG

1. Defendants' conduct violates the FDCA, FTC Act, and COVID-19 CPA

As alleged in the complaint, Earth Tea is a drug, because Defendants' labeling claims that it is effective against a specific disease: COVID-19. Compl. ¶¶ 18-20, 24-29. Defendants' claims include: "EARTH TEA PROVEN TREATMENT FOR COVID-19 WORKS WITHIN MINUTES GET OUT OF QUARANTINE WITHIN 24HRS GUARANTEED." *Id.* at ¶ 26; and "Vax or Not Grab 2 bottles . . . in case Covid19 [] hits. . . . DON'T DIE FROM COVID19. . . . We are 100% sure we can save you!" *Id.* at ¶ 26.

Under the FDCA, before a product can be sold with such claims, the product must be either approved by FDA or generally accepted as safe and effective ("GRASE") in the scientific

community. *Id.* at ¶¶ 18-22. Earth Tea is neither. ¶¶*Id.* at ¶¶ 67-72. Therefore, Earth Tea's marketing violates the FDCA. *Id.* at ¶¶ 71-72.

Earth Tea is also considered a drug under the FTC Act. *Id.* at ¶ 13. Because Defendants lack any competent and reliable scientific evidence to prove the truth of their labeling claims touting Earth Tea as effective against COVID-19, these marketing claims are false, misleading or unsubstantiated, and constitute deceptive acts and practices. *Id.* at ¶¶ 44-46. The single, unpublished 15-person study touted by Defendants lacks any control group to establish that Earth Tea performed any better than a placebo, and it contains no documentation or supporting data analysis for its single nebulous efficacy claim. It thus does not qualify as competent and reliable scientific evidence of any benefit related to COVID-19, much less support Defendants' myriad claims of efficacy against COVID-19. *Id.* at ¶¶ 27-29. Therefore, Defendants' labeling claims for Earth Tea – which are material to consumers' decisions because they relate to COVID-19 prevention and treatment – are deceptive acts or practices, and false advertisements that violate the FTC Act and the COVID-19 CPA. *Id.* at ¶¶ 45-50, 52-59, 62-63.[5]

2. Earth Tea is a drug, and therefore the dietary supplement regulations do not apply to it

In his Rule 12(b) Motion, Defendant Sinclair asserts: "Earth tea extra strength is a 100% Natural Supplement Drink, marketed as a natural Immune Drink, that May help support the immune system, to help our body overcome issues. Based on the above facts A, B, C, and D posted on the FDA website, I the Defendant ask that the court grants Motion to Dismiss Plaintiff's statements contained in the following Paragraphs . . . ." 12(b) Mot. at 2.

[5] The United States also alleges that Defendants have been aware of the COVID-19 CPA since at least February 18, 2021, when Defendants received a joint warning letter from FTC and FDA detailing Defendants' violations. Compl. ¶¶ 36, 56; *see also supra* n.4.

The law is clear that if a product is promoted to treat or cure specific diseases, it is a drug under the FDCA. In the course of affirming convictions relating to the introduction of an unapproved new drug, the Second Circuit agreed "with the district court that, as a matter of law, if [defendant's product] was promoted as a treatment or cure for cancer, AIDS, or other diseases," then it is a drug regulated under the FDCA. *United States v. Writers & Research, Inc.*, 113 F. 3d 8, 11, 13 (2d Cir. 1997) ("[I]f an article is intended for use in the diagnoses, cure, mitigation, treatment, or prevention of disease in man it is defined as a drug."). In *United States v. Berst*, the court rejected claims similar to the ones Defendant Sinclair makes here – that his product is a dietary supplement, and subject to regulation as a dietary supplement, not as a drug:

> DSHEA authorizes certain types of claims regarding dietary supplements, but expressly prohibits claims that dietary supplements can "diagnose, mitigate, treat, cure, or prevent a specific disease or class of diseases." . . . . Therefore, a product that meets the "dietary supplement" definition is still a drug under the FDCA if it is labeled for curing or treating disease.

Berst, No. 6:11-cv-6370-TC, 2012 WL 4361408, at *7 (D. Ore. 2012) (quoting FDCA, including DSHEA).

Moreover, under the FDCA, a dietary supplement may also be a drug if it meets the definition of a drug. *See* 21 U.S.C. 321(g)(1). Interpreting Section 321, the Second Circuit has ruled that "even if [a product] were to qualify as a dietary supplement under 321(ff), that status would not be relevant to the determination whether [that product] is a drug within the meaning of 321(g)(1)." *United States v. Ten Cartons, More or Less . . . Ener-B Vitamin B-12*, 72 F. 3d 285, 287 (2d Cir. 1995). "For many years, courts have found that when healing powers are attributed to foods they become drugs within the meaning of the FDCA, ... [and] the Second Circuit read the statute as Congress's 'judgment that a product is subject to regulation as a drug if certain promotional claims are made for it.'" *United States v. Lebeau*, No. 10-CR-253, 2016 WL

447612, at *7 (E.D. Wisc. Feb. 3, 2016) (*quoting United States v. Article . . . Consisting of 216 Cartoned Bottles*, 409 F. 2d 734, 739 & n.3 (2d Cir. 1969)). Thus, consistent with applicable case law, even if Defendants' product met the statutory definition of dietary supplement and was properly promoted and labeled as such, that would not insulate Defendants from the unapproved new drug violations at issue in this case.

The United States tried to avoid this very litigation by reaching out to Defendant Sinclair before filing. Starting in 2021, the government warned Defendant Sinclair that his use of disease-specific claims in the product's labeling make the product a drug. For example, in February 2021, the United States informed Defendant Sinclair as follows:

> The FDA has observed that your website . . . offers the product Earth Tea Extra Strength for sale in the United States and that this product is intended to mitigate, prevent, treat, diagnose, or cure COVID-19 in people. Based on our review, this product is an unapproved new drug sold in violation of . . . the Federal Food, Drug, and Cosmetic Act (FD&C Act), 21 U.S.C. [section] 355(a). . . . We request that you take immediate action to cease the sale of any unapproved and unauthorized products for the mitigation, prevention, treatment, diagnosis, or cure of COVID-19.

See Feb. 18, 2021 Joint FDA & FTC Warning Ltr. at 1-2 (excerpting Earth Tea labeling representing Earth Tea as effective for the treatment or prevention of COVID-19).

As the Complaint amply alleges, Earth Tea's product labeling contains numerous claims that Earth Tea is effective against COVID-19, which qualify this product as a drug, and other circumstances of the product make it an unapproved new drug. *See, e.g.*, Compl. ¶¶ 23-34, 66-72. Thus, Defendant Sinclair's apparent effort to dismiss this suit by contending that Earth Tea is a dietary supplement fails.

3. Defendant Sinclair's Rule 11 Motion's Argument that Dietary Supplement Regulations Require Evidence That a Product is False, Misleading or Harmful Are Likewise Irrelevant

Defendant Sinclair begins his Rule 11 motion with an excerpt from a website indicating that, in any proceeding brought under subsection (a) of DHSEA, "the burden of proof shall be on the United States to establish that an article or other such matter is false or misleading." Rule 11 Mot. at 2. Based on this provision relating to dietary supplement regulation, Defendant Sinclair claims: "Facts, B4B Earth Tea has no negative feedbacks or complaints posted Online. Plaintiff makes claims with no proof, Plaintiff makes accusations with no evidence to show cause. For the above reasons I the Defendant ask that the court please grant Motion to Dismiss pursuant to Rule 11." Rule 11 Mot. at 2. As noted above, DSHEA does not apply to the instant Complaint, and thus neither the burdens of proof nor any element of DSHEA provides any support to Defendant Sinclair's motions.

To the extent that Defendant Sinclair is claiming that the United States has failed to demonstrate harm to consumers, that claim also fails. A Complaint is required only to include allegations that, if accepted as true, are sufficient to state a plausible claim for relief.[6] In addition, the United States need not allege any harm to consumers to defeat a motion to dismiss as to its claims under the FDCA or the FTC Act (including the COVID-19 CPA). The Second Circuit has held that, if a statute authorizes injunctive relief, the United States need not show injury to the public: "The passage of the statute is, in a sense, an implied finding that violations will harm the public . . . . No specific or immediate showing of the precise way in which violation of the law will result in public harm is required." *United States v. Diapulse Corp. of Am.*, 457 F. 2d 25, 28 (2d Cir. 1972). The FDCA authorizes injunctive relief at 21 U.S.C. 332(a), and the FTC Act authorizes injunctive relief at 15 U.S.C. 53(b) (Section 13(b)). Given that the Complaint alleges violation of the statutes at issue, which do not require any allegations of public harm, Defendant

[6] *See supra* Section II and cases cited therein.

Sinclair's arguments based on injury or harm should be rejected. As noted in Section III.A.1 above, the United States' allegations in the Complaint, including those made in the context of claims under the FTC Act and COVID-19 CPA pertaining to Defendants' false, misleading or unsubstantiated assertions in Earth Tea's labeling, are wholly sufficient to state claims under the relevant statutes.[7]

B. DEFENDANT SINCLAIR'S ARGUMENT THAT THE UNITED STATES' COMPLAINT SHOULD BE DISMISSED FOR LACK OF EVIDENCE IS FLAWED, BECAUSE NO EVIDENCE IS CURRENTLY REQUIRED

Defendant Sinclair next argues that the United States has not (yet) brought forth evidence to substantiate its claims. This argument, too, should be rejected. It is black letter law that, in the context of a motion to dismiss, no proof is required, and all the plaintiff's allegations must be accepted as true. *See supra* Section II and cases cited therein. Moreover, virtually all the evidence of Defendants' labeling for Earth Tea is pulled directly from public statements Defendants made promoting Earth Tea on the internet and social media. Compl. ¶¶ 26-30, 34. In light of all the foregoing, this argument by Defendant Sinclair must be rejected.

C. DEFENDANT SINCLAIR'S INVOCATION OF THE FIFTH AND FOURTEENTH AMENDMENTS AND THE NEW YORK FALSE CLAIMS ACT ARE LIKEWISE IRRELEVANT

The Fifth and Fourteenth Amendments to the U.S. Constitution and the New York False Claims Act do not apply here.

Even if Defendant Sinclair's motions could be construed to be a Fifth Amendment Due Process Clause argument, that argument fails because Defendant Sinclair has not identified a liberty interest for which the protection is sought, let alone established that the United States has infringed on it.

[7] Compl. ¶¶ 43-44, 51-58.

In the course of dismissing a due process claim based on very similar facts,[8] the court in *United States v. Berst* stated:

> In order to invoke the protection of the Due Process Clause, a plaintiff must first establish the existence of a liberty interest for which the protection is sought. . . . Here, defendant has not established the existence of a liberty interest to work as a master herbalist. Moreover, even if he had established such, he had not established that the government has infringed on his right. The government is not preventing defendant from selling herbs and supplements. Instead, it is preventing him from selling herbs and supplements with labeling claims that cause the products to be drugs under the FDCA without having the labeling claims evaluated by the FDA. I find that defendant has not established a Fifth Amendment claim.

2012 WL 4361408, at *8; *see also United States v. Lebeau*, No. 10-CR-253, 2016 WL 447612, at *10 (E.D. Wisc. Feb. 3, 2016) (noting, in the course of rejecting a Fifth Amendment due process argument and affirming a conviction for introduction of an unapproved new drug, that "[r]egarding due process, [the defendant] was convicted based on his intent, as evidenced by his promotions and statements."); *United States v. General Nutrition, Inc.*, 638 F. Supp. 556, 558, 561 (W.D.N.Y. 1986) (rejecting defendants' due process challenges that were based on claims that FDA improperly classified their product as a drug, as opposed to a food). For the reasons provided by these courts, any Fifth Amendment due process claim here should fail.

The Fourteenth Amendment to the United States Constitution concerns primarily state laws and actions, and it has no bearing on this federal lawsuit. *See* U.S. Const. amend. XIV. Likewise, the New York False Claims Act is a state law that plays no part in the United States' claims in this case. *See* N.Y. State Fin. Law § 187 *et seq.*; *see also United States v. Northern Adult Daily Health Care Center*, 205 F. Supp. 3d 276, 286 (E.D.N.Y. 2016) (indicating that the

[8] The defendant in *Berst* was also a *pro se* defendant and sole owner of a company that claimed its products (herbal remedies) cured specific diseases, and continued notwithstanding receipt of a warning letter from FDA, but maintained that the products should nonetheless be regulated as dietary supplements, not drugs. *See Berst*, 2012 WL 4361408, at *1, *7.

New York False Claims Act is a state law that imposes liability for knowingly making a false record or a false statement).

D. THE PRO SE MOTIONS TO DISMISS FILED BY DEFENDANT SINCLAIR FAIL TO SPECIFY WHETHER THEY ARE SOLELY ON BEHALF OF DEFENDANT SINCLAIR, OR ALSO THE TWO CORPORATE DEFENDANTS THAT MAY ONLY APPEAR THROUGH AN ATTORNEY

The United States will assume, for present purposes only, that Defendant Sinclair filed the motions on behalf of the company defendants.[9] That is improper. Companies can only appear through and be represented by attorneys. It is well-settled that federal law "prohibits the practice of law . . . on behalf of anyone other than himself or herself by a person who is not an admitted member of the Bar." *Gabayzadeh v. Taylor*, 639 F. Supp. 2d 298, 301-02 (E.D.N.Y. 2009) ("'[A] nonlawyer . . . has no right to represent another entity . . . in a court of the United States' . . . 'A pro se [party] may not represent the interests of another individual or corporate entity in a civil proceeding.'") (quoting *Kahn v. Gee Broadcasting, Inc.*, No. 07-CV-1370, 2007 WL 1176734, at *1 (E.D.N.Y. Apr. 20, 2007)) (internal citations omitted).[10]

Courts in this Circuit have refused to consider motions filed *pro se* on purported behalf of a corporation, and warned *pro se* litigants that the failure of a corporation to appear through an attorney may lead to entry of a default judgment against the corporation. *See Testaccio v. Rahim*, 21-CV-1916 (JS) (AYS), 2021 WL 1999411, at *1-*2 (E.D.N.Y. May 19, 2021); *Grace v. Bank Leumi Trust Co. of New York*, 443 F. 3d 180, 192 (2d Cir. 2006)).

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[9] Defendant Sinclair's motions do not specify whether they are filed on behalf of the two corporate defendants. In them, Defendant Sinclair merely references himself as "I the Defendant." Rule 11 Mot. at 2; Rule 12(b) Mot. at 2. If the motions were filed only on behalf of Defendant Sinclair, then the company defendants have failed to file an answer or motion to dismiss by the extended deadline of June 7, 2022, that the Court set for them.

[10] Attached, at Exhibit A, please find an Affidavit Concerning Local Rule 7.2.

Counsel for the United States has informed Defendant Sinclair that he could not appear on behalf of the two company defendants and was required to retain an attorney to represent them.[11] In addition, Defendant Sinclair sought an extension of the deadlines for filing responsive pleadings specifically to find an attorney, [Dkt. 7], and the Court granted a 30-day extension until June 7, 2022 for this purpose, [Dkt. 8].

III. CONCLUSION

For all of the reasons set forth above, Defendant Sinclair's Motions to Dismiss should be denied.

Dated: June 15, 2022

Respectfully submitted,

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[11] The United States conveyed this to Defendant Sinclair first during a March 4, 2022 telephone call, contemporaneous with the United States' filing of the Complaint; again during a subsequent March 17, 2020 telephone conversation; and also on May 19, 2022, by email, when the Department of Justice followed up regarding Sinclair's stated intent to file the instant motions.

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